Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Comparison of therapeutic effect of green tea mouthwash and nystatin suspension in denture stomatitis

Protocol summary

Summary

Objectives: In this study the untifungal effect of Green tea mouthwash 0.5% on patients with denture stomatitis was examined. Design: Twenty two patients with denture stomatitis who had been referred to the department of oral medicine in sari faculty of dentistry in spring 1396 were divided into two groups. Setting and conduct: One group received treatment with green tea mouthwash 0.5% four times a day and each time use 15 milliliter about 2.5 table spoon for two weeks. Another group use nystatin suspension 100000 u/l four times a day and each time use 1 milliliter about 20 drops for two weeks. Participants including majoreligibility criteria: Absence of using denture in sleeping; No use of untifungal drugs and antibiotics and corticosteroid in past 1 month; No allergy to nystatin suspension; Absence of immunodeficiency; Absence of alzheimer; Absence of cyhalological disorders; Absence of musculoskeletal disorders; Ability to consume mouthwash. Main outcome messures: First examination is before treatment is run to check the length and the width of lesions.7 days after first examination, in the second examination length and width are written.14 days after first examination, in the third examination length and width are written again.the microbial culture is done before treatment and after 14 days. Finally the data of two groups are compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017060334314N1**
Registration date: **2017-07-12, 1396/04/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-07-12, 1396/04/21

Registrant information

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Name of organization / entity
Mazandaran university of medical sciences
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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2017-06-26, 1396/04/05

Expected recruitment end date

2017-07-01, 1396/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of therapeutic effect of green tea mouthwash and nystatin suspension in denture stomatitis

Public title

comparison of therapeutic effect of green tea mouthwash in the treatment of stomatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Absence of using denture in sleeping;

No use of untifungal drugs and antibiotics and corticosteroid in past 1 month; No allergy to nystatin suspension; Absence of immunodeficiency; Absence of alzheimer; Absence of cyhalological disorders; Absence of musculoskeletal disorders; Ability to consume mouthwash

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **22**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
The number of sampling is chosen by convenient sampling. After that, by random sampling, one group of samples are located in the first intervention group, another group of samples in the second intervention group. Each individual is assigned a number and then randomly chosen so the objectivity of the research is reached.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The ethics committee of Mazandaran University of Medical Sciences

Street address
Vice chancellor for research, Mazandaran university of medical science, The martyr Motahhari square, Street teacher

City
Sari

Postal code
48157-3391

Approval date
2017-04-22, 1396/02/02

Ethics committee reference number
IR.MAZUM.REC.96.2948

Health conditions studied

1

Description of health condition studied
denture stomatitis

ICD-10 code
B37.0

ICD-10 code description
Candidal stomatitis Oral thrush

Primary outcomes

1

Description
length and width of lesions

Timepoint
Before intervention, one week after the beginning of intervention, two weeks after the beginnig of intervention

Method of measurement
calliper _ cm

2

Description
colonies number

Timepoint
Before intervention, two weeks after the beginnig of intervention

Method of measurement
Number of fungi

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group use the green tea mouthwash 0.5% 4 times a day each time 15 milliliter about two and half table spoon. They should use it after washing their mouth and use it for one minute in their mouth. They should refrain from eating and drinking for about one hour. It should be used for two weeks.

Category
Treatment - Drugs

2

Description
The second intervention group use the nystatin suspension 1000000 u/l four times a day and each time use one milliliter about 20 drops. They should use it after washing their mouth and use it for one minute in their mouth. They should refrain from eating and drinking for about one hour. It should be used for two weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dental Clinic, Mazandaran University of Medical Sciences

Full name of responsible person
Dr.Anahita Ghorbani

Street address
Dental clinic, Khazar Blvd, Khazar square Sari Mazandaran

City
Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Mazandaran University of Medical Sciences

Full name of responsible person
Ahmad Ali Enayati

Street address
Vice chancellor for research, The martyr Motahhari square, Street teacher

City
Sari

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice chancellor for research, Mazandaran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Dr.Anahita Ghorbani

Position
Professor / Associate Professor, School of Dentistry

Other areas of specialty/work

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty